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SENATE BILL 5470

State of Washington 59th Legislature 2005 Regular Session

By Senators Franklin, Thibaudeau, Keiser, Kline, Poulsen, Berkey, Haugen, McAuliffe, Rockefeller, Shin and Kohl-Welles; by request of Governor Gregoire

Read first time 01/26/2005. Referred to Committee on Health & Long-Term Care.

- 1 AN ACT Relating to importation of prescription drugs from Canadian
- 2 wholesalers; amending RCW 18.64.046; adding a new section to chapter
- 3 18.64 RCW; and creating new sections.

all of their prescription drug needs.

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- 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:
- 5 NEW SECTION. Sec. 1. The legislature finds that as consumers' prescription drug costs continue to rise, people across the state of 6 7 Washington are seeking opportunities to purchase lower 8 prescription drugs from Canada for their personal use. The state has 9 a strong interest in promoting the safe use of prescription drugs by 10 consumers in Washington state. To address this interest, the legislature intends to seek authorization from the federal government 11 to license Canadian prescription drug wholesalers, thereby providing 12 licensed retail pharmacies the opportunity to purchase prescription 13 14 drugs from approved Canadian wholesalers and pass those savings on to 15 consumers, and providing consumers the opportunity to purchase 16 prescription drugs from a trusted community pharmacist who is aware of

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NEW SECTION. Sec. 2. A new section is added to chapter 18.64 RCW to read as follows:

- (1) By September 1, 2005, the board shall, in consultation with the department and the health care authority, submit a waiver request to the federal food and drug administration that will authorize the state of Washington to license Canadian prescription drug wholesalers under RCW 18.64.046, thereby providing retail pharmacies licensed in Washington state the opportunity to purchase prescription drugs from approved Canadian wholesalers and pass those savings on to consumers. The waiver shall provide that:
- (a) Canadian prescription drug wholesalers meet the requirements of RCW 18.64.046 and any rules adopted by the board to implement those requirements;
- (b) The board must ensure the integrity of the prescription drug products being distributed by:
 - (i) Requiring that prescription drugs purchased from Canadian wholesalers originate only from approved manufacturing locations;
 - (ii) Routinely testing prescription drugs purchased from Canadian wholesalers for safety;
 - (iii) Establishing safe labeling, tracking, and shipping procedures for prescription drugs purchased from Canadian wholesalers; and
 - (iv) Closely monitoring compliance with RCW 18.64.046 and any rules adopted to implement the waiver;
 - (c) The prescription drugs purchased from Canadian wholesalers must be limited to those for which potential savings to consumers can be demonstrated;
 - (d) To ensure that the program benefits those consumers without insurance coverage for prescription drugs who are most in need of price relief, prescription drug purchases from pharmacies under the waiver will be limited to those not eligible for reimbursement by third party insurance coverage, whether public or private; and
 - (e) Savings associated with purchasing prescription drugs from Canadian wholesalers will be passed on to consumers.
- 34 (2) By December 1, 2005, the board, in consultation with the 35 department and the health care authority, shall submit a detailed 36 implementation plan to the governor and appropriate committees of the 37 legislature that details the mechanisms that the board will use to

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- implement each component of the waiver under subsection (1) of this section.
- 3 (3) The board shall adopt rules as necessary to implement this act.

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- Sec. 3. RCW 18.64.046 and 2004 c 52 s 3 are each amended to read as follows:
- (1) The owner of each place of business which sells legend drugs and nonprescription drugs, or nonprescription drugs at wholesale shall pay a license fee to be determined by the secretary, and thereafter, on or before a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, a like fee to be determined by the secretary, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell legend drugs and nonprescription drugs or nonprescription drugs at wholesale at the location specified for the period ending on a date to be determined by the secretary, and each such owner shall at the time of payment of such fee file with the department, on a blank therefor provided, a declaration of ownership and location, which declaration of ownership and location so filed as aforesaid shall be deemed presumptive evidence of the ownership of such place of business mentioned therein. It shall be the duty of the owner to notify immediately the department of any change of location and ownership and to keep the license of location or the renewal thereof properly exhibited in such place of business.
- (2) Failure to conform with this section is a misdemeanor, and each day that the failure continues is a separate offense.
- (3) In event the license fee remains unpaid on the date due, no renewal or new license shall be issued except upon compliance with administrative procedures, administrative requirements, and fees determined as provided in RCW 43.70.250 and 43.70.280.
- (4) No wholesaler may sell any quantity of drug products containing ephedrine, pseudoephedrine, phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products to persons within the state of Washington exceed five percent of the wholesaler's total prior monthly sales of nonprescription drugs to persons within the state in March through October. In November through February, no wholesaler may sell any quantity of drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers if the total monthly sales of these

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products to persons within the state of Washington exceed ten percent of the wholesaler's total prior monthly sales of nonprescription drugs to persons within the state. For purposes of this section, monthly sales means total dollars paid by buyers. The board may suspend or revoke the license of any wholesaler that violates this section.

- (5) The board may exempt a wholesaler from the limitations of subsection (4) of this section if it finds that the wholesaler distributes nonprescription drugs only through transactions between divisions, subsidiaries, or related companies when the wholesaler and the retailer are related by common ownership, and that neither the wholesaler nor the retailer has a history of suspicious transactions in precursor drugs as defined in RCW 69.43.035.
- (6) The requirements for a license apply to all persons, in Washington and outside of Washington, <u>including those in Canadian provinces</u>, who sell both legend drugs and nonprescription drugs and to those who sell only nonprescription drugs, at wholesale to pharmacies, practitioners, and shopkeepers in Washington.
- (7) No wholesaler may sell any quantity of ephedrine, pseudoephedrine, phenylpropanolamine, or their salts, isomers, or salts of isomers, to any person in Washington other than a pharmacy licensed under this chapter, a shopkeeper or itinerant vendor registered under this chapter, or a practitioner as defined in RCW 18.64.011. A violation of this subsection is punishable as a class C felony according to chapter 9A.20 RCW, and each sale in violation of this subsection constitutes a separate offense.
- (8) If the board is unable to develop a reciprocal licensing agreement with Health Canada or an applicable Canadian province, the board shall develop a process to license participating Canadian wholesalers through on-site inspection and certification.
- NEW SECTION. Sec. 4. If any part of this act is found to be in conflict with federal requirements that are a prescribed condition to the allocation of federal funds to the state, the conflicting part of this act is inoperative solely to the extent of the conflict and with respect to the agencies directly affected, and this finding does not affect the operation of the remainder of this act in its application to the agencies concerned. Rules adopted under this act must meet federal

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- 1 requirements that are a necessary condition to the receipt of federal
- 2 funds by the state.

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